DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 21, 2015

MRI Interventions, Inc.
% John J. Smith, MD, JD
Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Re: K142505
Trade/Device Name: ClearPoint System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW, ORR
Dated: September 22, 2015
Received: September 22, 2015

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142505

Device Name
ClearPoint System

Indications for Use *(Describe)*

The ClearPoint System is intended to provide stereotactic guidance and operation of instruments or devices during the planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. The ClearPoint System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion. The System is intended for use only with 1.5 and 3.0 Tesla MRI scanners.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K142505

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the MRII ClearPoint System.

1. Company Making the Submission:

Name of Owner:	**MRI Interventions, Inc.**
Address:	**5 Musick** **Irvine, CA 92618**
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Fax:	**949-900-6834**
Contact:	**Pete Piferi**
E-mail:	**ppiferi@mriinterventions.com**
Date Prepared:	**October 21, 2015**

2. Device Name:

Common Name:	Neurological Stereotaxic Instrument
Proprietary Name:	ClearPoint System
Classification Name:	Stereotaxic Instrument
Regulatory Class:	II
Regulation Number:	21 C.F.R. § 882.4560
Product Code:	ORR, HAW

3. Predicate Device:

MRII ClearPoint System, K111073

4. Device Description:

The ClearPoint System is comprised of a workstation laptop with software, the SMARTGrid™ MRI-Guided Planning Grid, the SMARTFrame™ MRI-Guided Trajectory Frame, the SMARTFrame™ Accessory Kit and the SMARTFrame™ Hand Controller.

The SMARTGrid and associated Marking Tool are designed to assist the physician to precisely position the entry hole as called out in the trajectory planning software. The SMARTFrame is an Adjustable Trajectory Frame (ATF) that provides the guidance and fixation for neurosurgical tools. The MRI visible fluids of the Targeting Cannula along with the fiducial markers in the base of the frame allows for trajectory feedback when the physician views the MRI images, makes changes and confirms with subsequent MR images.

The ClearPoint System can be used with any MRI-compatible head fixation frame to immobilize the patient's head with respect to the scanner table, as well as with any imaging coil(s) that meet the physician's desired imaging quality. MRI Interventions also supplies an optional head fixation frame and imaging coil(s) that can be used with the ClearPoint System.

The ClearPoint Workstation includes the following:

1. ClearPoint Workstation Software (for trajectory planning and monitoring)
2. Laptop Computer

The hardware components of the ClearPoint System are the SMARTFrame and Accessories. They are all single use devices that are provided sterile. They include the following:

1. SMARTGrid Pack (interacts with the software to determine the desired location of the burr hole)
    a. Marking Grid
    b. Marking Tool
2. SMARTFrame Pack (SMARTFrame or SMARTFrame XG)
    a. SMARTFrame ("ATF") with Base
    b. Centering Tool
    c. Dock
    d. Device Lock (2 different diameters)
    e. Screwdriver
    f. Roll Lock Screw and Washer
3. Rescue Screws (Extra Titanium Screws)
4. Hand Controller (for use with the ATF) and Thumbwheel Extension
5. Accessory Pack
    a. Peel-away Sheath
    b. Stylet
    c. Lancet
    d. Depth Stop
    e. Ruler
6. Scalp Mount Base
7. Guide Tube and Device Guide Packs (Guide Cannulas)
8. SmartTip MRI Hand Drill and Drill Bit Kit
9. MRI Neuro Procedure Drape, with Marker Pen and Cover
10. MR Camera Fiberscope Accessory Kit
11. SmartFrame MR Fiducial

Each of the above packs is sold separately. Each is intended to be used with the ClearPoint Workstation.

5. Indications for Use:

The ClearPoint System is intended to provide stereotactic guidance and operation of instruments or devices during the planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. The ClearPoint System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion. The System is intended for use only with 1.5 and 3.0 Tesla MRI scanners.

6. Comparison of the Technological Characteristics of the Device with the Predicate Device:

Modifications to the predicate ClearPoint System are as follows:

a) The Scalp Mount is a modified base for the existing ClearPoint ATF allowing attachment through the scalp to the skull instead of directly to the skull via a relatively large incision.
b) The SMARTFrame XG is a modified tower of the ClearPoint ATF allowing the exchange of Guide Cannulas, e.g. removal of the existing Guide Cannula and replacement with a Guide Cannula(s), allowing larger devices to be utilized in neurological procedures.

c) Evolutionary changes within the ClearPoint System software.
d) Minor modifications of pre-existing accessories for the ClearPoint System.

	ClearPoint System K111073	**ClearPoint System (Modified)**
Classification	21 CFR 882.4560	21 CFR 882.4560
Product Code	ORR, HAW	ORR, HAW
Intended Use	The ClearPoint System is intended to provide stereotactic guidance and operation of instruments or devices during the planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. The ClearPoint System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion. The System is intended for use only with 1.5 and 3.0 Tesla MRI scanners.	The ClearPoint System is intended to provide stereotactic guidance and operation of instruments or devices during the planning and operation of neurological procedures within the MRI environment and in conjunction with MR imaging. The ClearPoint System is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode insertion. The System is intended for use only with 1.5 and 3.0 Tesla MRI scanners.
Environment	MRI Suite	MRI Suite
Sterilization	EO 10^{-6} SAL	EO 10^{-6} SAL
SmartGrid Pack	MRI Planning Grid & Marking Tool	MRI Planning Grid & Marking Tool
SmartFrame Pack	SmartFrame ATF, Scalp Mount Base, Bone Screws, Screwdriver, Centering Tool, Dock and Lock, Roll Lock Screw with Washer, Extra Titanium Screws	SmartFrame XG, Scalp Mount Base, Bone Screws, Scalp Mount Base, Screws, Stand-Off Pins, Screwdriver, Centering Tool, Dock and Lock, Roll Lock Screw with Washer, Rescue Screws (packaged separately)
Hand Controller	Hand Controller	Thumbwheel Extension (Light Hand Controller)
Accessory Kit	Peel-away Sheath, Stylet, Depth Stop, Ruler	Peel-away Sheath, Lancet, Stylet, Depth Stop, Ruler
Targeting Cannula ID	0.0825”	0.0825”
Targeting Cannula Material	Ultem and PEEK	Ultem and PEEK
Guide Tube / Device Guide ID	0.052, 0.068, 0.074”	0.0938 & 0.141”
Guide Tube / Device Guide Material	Ultem and PEEK	Ultem and PEEK
Packaging	Sterile, Sealed Tray, Inside Sterile Tyvek Pouch	Sterile, Sealed Tray, Inside Sterile Tyvek Pouch
Targeting Accuracy	±1.5mm @ ≤125mm	±1.5mm @ ≤125mm
Software	1.0	1.5

The Scalp Mount Base performs exactly the same function as the original SmartFrame Base, but is mounted through the patient’s scalp to the skull instead of

directly to the scalp via a relatively large incision. The modification to the original Base was made to allow less invasive procedures to be performed with the SmartFrame.

The SmartFrame XG is a modification to the previously cleared SmartFrame ATF that is sold as a separate product. The need for the SmartFrame XG arose from physicians' desire to use ClearPoint and the SmartFrame for precision placement of MRI Compatible Biopsy Needles, Shunt Catheters for cyst drainage, and laser ablation catheters. The changes had no impact on use of the SmartFrame. The same Dock-and-Lock system used in the original SmartFrame ATF can be used with the SmartFrame XG. No software changes were necessary for the SmartFrame XG. The SmartFrame XG is fully interchangeable with all other SmartFrame components and accessories.

7. Performance Data:

The performance testing performed for the predicate ClearPoint System (K111073) is fully applicable to the modified ClearPoint System performance. Specifically, the following testing that was performed on the predicate device is fully applicable to the modified ClearPoint System:

- Accuracy Testing, including MRI Device Accuracy Testing, System Accuracy in a Water Phantom and System Accuracy in a Cadaver. These test results demonstrate the targeting accuracy of the predicate ClearPoint System (K111073) when used in conjunction with MRI scanner software. The results support the safe and effective use of the ClearPoint System to guide a device to a brain target with an error less than 1.5mm at ≤125mm.
- ClearPoint System Safety Testing with 1.5T and 3.0T MRI scanners.

In addition, the accuracy testing for the predicate ClearPoint System (K111073) was repeated for the modified ClearPoint System to validate a targeting accuracy for the ClearPoint System using the raised Scalp Mount frame. The results of this testing confirm the targeting accuracy of the device with an error less than 1.5mm at ≤125mm from the insertion point.

No additional sterility testing was performed. Additional biocompatibility tests were performed on the Device Guides as described below.

The ClearPoint System was modified in conformance with the company's design control procedures. Design inputs provided the requirements for the respective product specifications. Design Verification was performed relative to these specifications with acceptable results. Risk analysis was performed with mitigation of all identified risks to acceptable levels. The tests and risk analysis demonstrated that the modified ClearPoint System functions as intended and is substantially equivalent to the legally marketed ClearPoint System. A summary of the performance testing that was conducted on the subject device is presented in the table below.

The risks of the modified ClearPoint System were further mitigated through labeling revisions to include a warning that end users should not use the system with instruments longer than 30cm in length, as the accuracy of the system has not been established with instruments longer than this length.

Test	Test Method Summary	Results
Accuracy of Scalp Mount Base	The Scalp Mount Base was tested using a water phantom to verify system accuracy was maintained.	Pass
Accuracy of Large Bore ATF and Device Guide	A cadaver study was used to verify the accuracy of the Large Bore ATF and Device Guide.	Pass
Accuracy of SmartFrame XG and Device Guides	The SmartFrame XG and Device Guides were verified to maintain accuracy using a photomapping digitizer program and a cylindrical phantom test.	Pass
Accuracy of ClearPoint Components, Assemblies and System	Accuracy of the system under adverse and worst case conditions evaluated to ensure Stylet location was maintained.	Pass
Targeting Cannula Aging	One- and two-year accelerated heat aging tests for the Targeting Cannula	13-Month Shelf Life
Biocompatibility of Device Guide	Cytotoxicity Study Using ISO Elution Method & ISO Skin Irritation Study in Rabbits	Pass

Software Verification and Validation

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for industry and FDA Staff, "Guidance for the content of premarket Submission for software Contained in Medical Devices." The software for this device represents a moderate level of concern. The system conforms to the DICOM standard to allow the transfer of images from the MR scanner.

Consensus Standards

The ClearPoint System complies with the following recognized consensus standards:

- NEMA PS 3.1-3.18 (2008) Digital Imaging and Communications in Medicine (DICOM) Set.
- AAMI/ANSI/ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing.
- ANSI/AAMI/ISO 1135-1 Sterilization of health care - products - Ethylene oxide - Part 1: Requirements for development, validation, and routine control of sterilization process for medical devices.

8. Conclusions:

The modifications to the ClearPoint System were made in conformance with the company's design control procedures and the performance testing performed for the predicate ClearPoint System (K111073), including accuracy testing and safety testing, is fully applicable to the modified ClearPoint System. Additional accuracy testing was performed with the raised Scalp Mount base to confirm the accuracy of the modified device with an error less than 1.5mm at ≤125mm from the insertion point.

The modified ClearPoint System has the same intended use and indications for use and similar technologies characteristics and principles of operation as the predicate ClearPoint System. The minor technological differences between the modified ClearPoint System and its predicate ClearPoint System raise no new issues of safety and effectiveness. Thus the modifications are substantially equivalent to the previously cleared ClearPoint System.